April 27, 2022
Japan Tissue Engineering Co., Ltd.

J-TEC announces application for marketing approval for stable vitiligo treatment Autologous Cultured Epidermis "ACE02"

Japan Tissue Engineering Co., Ltd. ("J-TEC", headquarters in Gamagori, Aichi Prefecture; President & CEO Ken-ichiro Hata) applied to the Ministry of Health, Labour and Welfare today to obtain marketing approval for autologous cultured epidermis containing melanocyte (development name: ACE02) as a regenerative medical product.

This development product is intended for the treatment of stable vitiligo (vitiligo vulgaris or piebaldism).

With the vision of "creating a future for regenerative medicine", J-TEC is contributing to the improvement of patient's quality of life (QOL) by promoting the creation of a regenerative medicine industry through the continuous development and marketing of new regenerative medical products and medical devices, as well as efforts to further promote the use of its existing products.


「ACE02」

Details

[Product Summary]

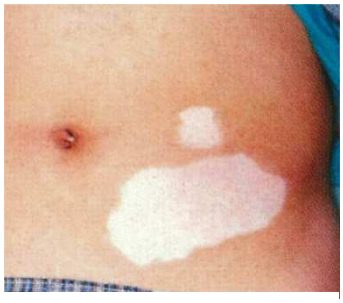
- "ACE02" is autologous cultured epidermis produced by harvesting the patient's own skin tissue, culturing cells isolated from it, and forming them into sheets containing melanocytes, which are then used to treat the patient him/herself.
- "ACE02" is transplanted to the area affected by stable vitiligo (vitiligo vulgaris or piebaldism) after the patient's epidermal layer has been shaved thin. The purpose of the product is to cure vitiligo by regenerating pigmentation through the supply of melanocytes by transplantation.
- Compared to existing forms of surgical therapy, "ACE02" is less invasive for the patient because an extensive area of depigmented skin can be treated all at once using a product made from a small area of skin tissue.

[Background and history]

Vitiligo is a disease in which the skin's pigment cells ("melanocytes") decrease, causing the skin to lose color and turn white. In particular, there is a growing need for ways of treating vitiligo vulgaris, an acquired disease in which melanocytes are destroyed, and piebaldism, a congenital disease that is caused by a genetic anomaly.

At present, vitiligo vulgaris is generally treated with topical application of a steroid or with ultraviolet irradiation. When these methods are not effective, surgical therapy is selected, but there are challenges in that it is difficult to uniformly treat a large area of skin at the same time.

To solve these problems, J-TEC has drawn upon the knowhow cultivated through the development of autologous cultured epidermis "JACE・" to develop the new product "ACE02", and a sponsor-initiated clinical trial of "ACE02" has been conducted since 2018.


Vitiligo vulgaris*

[Significance of development]

- Regeneration of pigmentation by this treatment method can contribute to eliminating patients' cosmetic concerns, which in turn can be expected to improve their QOL.
- The number of vitiligo vulgaris patients in Japan is approximately 150,000. The incidence of piebaldism is thought to be one in 20,000 to 100,000 people. "ACE02" will make it possible for J-TEC to provide a new treatment method to many more patients.

[Future outlook]

J-TEC announced its business plan for “ACE02” in the “Medium-Term Management Plan (Matters Related to Business Plans and Growth Potential)” dated May 11, 2021. Development is proceeding according to plan, so the impact on business results for the full fiscal year of 2022 is expected to be minimal. Any new factors that can be expected to exert a significant impact on J-TEC’s business results will be promptly disclosed.

* Source: Dermatological Clinical Asset 11: The Most Up-to-Date Guide to the Treatment of Chloasma and Vitiligo, 1st Edition (FURUE Masutaka) Nakayama Shoten Co., Ltd., Tokyo (2012)

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products whose corporate vision is “creating a future for regenerative medicine,” and has been a member of the Teijin Group since March 2021. As Japan’s top runner in regenerative medicine, J-TEC obtained marketing approval for autologous cultured epidermis “JACE”, Japan’s first regenerative medical product, in October of 2007, and began marketing the product in January of 2009. J-TEC then went on to obtain marketing approval for Autologous Cultured Cartilage “JACC” in July of 2021, for Autologous Cultured Corneal Epithelium “Nepic” in March of 2020, and for Autologous Cultured Oral Mucosal Epithelium “Ocural” in June 2021. "JACE" was Japan’s first regenerative medical product for use in plastic and reconstructive surgery. "JACC" was the first for use in orthopedic surgery, and "Nepic" was the first for use in ophthalmology. Of the 16 regenerative medical products that have been approved in Japan, four are J-TEC products.

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